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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,714	09/26/2003	Thomas P. Castellano	P 304309 304309	1147

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,714

Applicant(s)

CASTELLANO, THOMAS P.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9, 11, 13-14, 16 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Trautman et al (USPubN 2002/0091357). Regarding claims 1 and 20, Trautman discloses an injection apparatus with a single unitary housing (34), a group of about 30-40 lancets (90) and an injection spring (20 and 14) to drive the lancets axially out of the housing upon actuation.

Regarding claims 2 and 22, push button trigger (16) is in mechanical communication with the housing and actuates the device.

Regarding claim 3, the lancet base (44) is in direct mechanical communication with injection spring (20 and 14).

Regarding claim 4, the shear pin (62) contacts both the base and the housing.

Regarding claim 5, figure 7 shows multiple shear pins two sets of which are 180 degrees apart.

Regarding claims 7-9, the lancet base includes a guide (64) and the guide can be configured as four tabs. See paragraph 0037. The guides axially stabilize the base in the housing and axially stabilize the base for contact with the spring (20, 14) during administration of the drug.

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Regarding claim 11, the outside surface of the housing (34) is considered a finger rest.

Regarding claim 13, the push button trigger (16) as shown in figure 1 has a lateral ribbed surface which makes it non-slip.

Regarding claims 14 and 21, a cap (100) is removed from the housing prior to use.

Regarding claim 16, the lancets are coated with a vaccine or other pharmaceutical product. See paragraph 0056.

In general, see figures 2,4-7 and paragraphs 0035,0037,0053 and 0056.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 23-24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman in view of Kramer et al (USPN 5,451,210). Trautman meets the claim limitations as described above but fails to include the safety spring. However, Kramer provides a safety spring. See figure 6.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate the safety spring of Kramer into the invention of Trautman. The problem of inadvertant needle sticks is well known in the art and the use of springs at the injection end of device is a well know mechanism for providing retraction of the needle after use to prevent a needle stick. The motivation for incorporating the spring as taught by Kramer into the invention

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of Trautman would have been in order to enhance the safety of the device to the medical technician.

Claims 15 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer and in further view of Chiappetta (USPN 5,989,229). Trautman alone or Trautman in view of Kramer meet the claim limitations as described above but fail to teach a soft matrix in the cap. However, Chiappetta discloses such a matrix for enhancing the sterility of the needle prior to use. See figures 3-4.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate the soft matrix of Chiappetta into the invention of Trautman alone or Trautman in view of Kramer to enhance the sterility of the device prior to use.

Claims 10 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer. Trautman alone or Trautman in view of Kramer meet the claim limitations as described above but fail to teach specifically 36 lancets or one of the claimed drugs. However, at the time of the invention it would have been an obvious design choice by one skilled in the art to use 36 lancets or the claimed drugs. Applicant has not disclosed that 36 lancets over another number of lancets or the claimed drug over other drug provides an advantage, is used for a particular purpose or solves a stated problem. Additionally, one would expect the claimed particulars and the prior art device to perform equally well in administering an agent into or through the epidermis.

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Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trautman alone or in view of Kramer in further view of Herrick (USPN 102262). Trautman alone or Trautman in view of Kramer meet the claim limitations as described above but fail to teach a pair of finger rests. However, Herrick teaches such a finger rest. See figures 1-2.

At the time of the invention, it would have been obvious to incorporate the pair of finger rests as taught by Herrick into the invention of Trautman alone or Trautman in view of Kramer. Finger rests are well known in the syringe, lancet, needle art and are commonly used to provide the device with an enhanced grip for actuation of the device.

Response to Arguments

Applicant's arguments filed 1/23/06 have been fully considered but they are not persuasive. It is initially noted that many of the arguments are moot in light of the detailed rejection above.

Applicant argues that element 34 of Trautman cannot be considered the "housing" because the third element of claim 1 would not be met and element 34 would require other elements such as applicator 10 in order to perform an injection. This is not persuasive because claim 1 and claim 20 recite "an injection apparatus, comprising" which indicates that the apparatus could in fact contain more structures than claimed. Additionally, the apparatus comprises (at least in the independent claims) at least three elements, a housing, a group of lancets, and an injection spring. The claim does not read a housing containing a group of lancets and an injection spring. Furthermore, the new claim language of single and unitary is still exceedingly broad and does not further limit the invention. It is just coincidence that element 34

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is shown as a one piece structure. For instance if elements 10 and 34 were to be considered to be the housing, Trautment would still read on the claim limitations because once assembled and during use the "housing" being elements 10 and 34 would function as a single unitary housing.

The other arguments regarding the Trautman reference are obviated by the detailed rejection above.

Applicant argues that Chiappetta has nothing to do with enhancing sterility of the needle prior to use. However, the disclosure specifically states that the absorbent material could be antimicrobial such as alcohol or iodine. See 3:4+.

Applicant argues that there is no motivation for making the combination with the Herrick reference. One hand versus two hand operation is moot since all the devices are analogous. Instead the motivation was garnered from common knowledge by one skilled in the art and to provide an enhanced grip. See above. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Furthermore, Herrick does teach two finger rests in that even if the peripheral flange of Herrick does extend circumferentially around the device one skilled in the art would easily see that a continuous finger rest flange would provide an infinite number of finger rests around the periphery. Hence, the continuous flange would provide a pair of finger rests positioned at 180 degrees apart around the entire surface of the device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

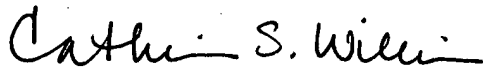
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams

April 2, 2006